DEFENDANT'S EXHIBIT A7

PRINTED: 10/23/2006
FORM APPROVED

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	330214	A. BUILDING _____ B. WING _____	07/28/2006

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NYU HOSPITALS CENTER	560 FIRST AVENUE NEW YORK, NY 10016

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S 000	INITIAL COMMENTS PFI # 1463 OPERATING CERTIFICATE # 7002053H NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF COMPLAINT # NY00027535. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOIONG COMPLIANCE MUST BE INCLUDED. #13	S 000		
S 134	405.2 (c) (1) GOVERNING BODY. Compliance with Federal, State and local laws. (1) The hospital shall comply with all applicable Federal, State and local laws, including the New York State Public Health Law, Mental Hygiene Law, and the Education Law. This Regulation is not met as evidenced by: Based on medical record review and staff interview, it was determined that the facility failed to comply with applicable New York State laws and statutes governing the practice of medicine. Findings include: Review of records and interviews conducted with administrative staff on 8/17/06 indicated that the facility was not in compliance with the Education Law of New York State (NYS). Specifically, it was noted that two persons were permitted to practice	S 134	Please note that this Statement of Deficiencies was received by the Chief Operating Officer of NYUMC on November 8, 2006. In the body of the letter that accompanied this Statement of Deficiencies we were instructed to prepare a Plan of Correction and submit our response by November 9, 2006. We notified Dr. William Marmer, our liason at the DOH, of the difficulties of responding within that timeframe. He agreed, and we sent a letter of understanding to him. *See Attachment A* S 134 405.2 (c) (1) 181 405.3 & S 328 405.4 (g) (1-2) (i-iii) In October of 2005, when NYU Hospitals Center discovered the possibility that fellows were practicing medicine in the Bariatric Surgery Fellowship Program without appropriate licensure, Dr. Thomas Riles, Chairman of the Department of Surgery, and the Chief Medical Officer, Dr. Max M. Cohen appointed an Ad Hoc Committee of the Medical Staff to investigate the situation. This committee reviewed the circumstances thoroughly and among its findings were: that the Program Director, supervised two fellows in the Program, prior to their obtaining a license or limited permit to practice medicine in New York; there were failures in oversight of the credentialing procedure within the Department of Surgery, as well as less than perfect checks in the Office of House Staff Affairs; that the Hospital contributed to this problem; and that the Program Dircetor permitted the physicians to practice medicine in violation of Hospital policy and State law. On February 2, 2006 this misconduct by the two fellows and the Program Director was reported to the Office of Professional Medical Conduct by Dr. Max M. Cohen. *See Attachment B* On February 15, 2006, Dr. Max M. Cohen notified the Program Director of the disciplinary actions that had been taken as a result of the Ad Hoc Committee of the Medical Staff's findings and recommendations: 1- Letter of Reprimand 2- Suspension of fellowship program in bariatric surgery *See Attachment C*	

Office of Health Systems Management

Chief Medical Officer — TITLE — 12/14/06 — (X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

STATE FORM A000 5U7A11 If continuation sheet 1 of

CONFIDENTIAL D 01023

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S 134	Continued From page 1 medicine in the facility in violation of that law, without the appropriate NYS licensure. It was also determined by the facility that an attending physician, who is a program director, aided the two persons to practice in violation of that law.	S 134	At the time of discovery that the fellows were seeing patients despite not being appropriately credentialed, one had already obtained a limited permit, but both were instructed to immediately stop practicing medicine at the hospital. We immediately reinforced our policy for the credentialing of residents and clinical fellows in ACGME and non- accredited programs. *See attachment D*	
S 181	405.3 (b) (7) ADMINISTRATION. Personnel. The chief executive officer develops and implements personnel policies and practices with regard to at least the following: (7) the verification of all applicable current licensure/certification. This Regulation is not met as evidenced by: Based on interview and record review, it was determined that facility administration failed to ensure that unlicensed physicians, without a limited permit, were not permitted to be hired and engage in the practice of medicine in the hospital. Findings include: Review of records and interview with administration 8/18/06 indicated that the facility permitted two persons with no license or limited permit to practice medicine in the hospital for a four month period in 2004 and 2005, respectively.	S 181	<u>S 134 405.2 (c) (1) 181 405.3 & S 328 405.4 (g) (1-2) (i-iii)</u> Two areas were identified as weaknesses in the credentialing process. The first was that house staff were given their ID badges prior to completing the credentialing process. Effective June 2006 the Security office no longer issues the NYU ID badge to house staff that have not cleared credentialing process. The second weakness noted was that computer access was granted prior to the resident completing the credentialing process. This has also been corrected. Health Information System access must be granted to allow the resident to train on the system, in advance of starting at NYU. Effective June 2006, if a resident does not 'clear' (complete the credentialing process) by their anticipated start date, then the Health Information System access is turned off until such time as they are cleared to begin resident training. We have a credentialing policy, which can be found at the link below and copy attached. *See Attachment D* http://www.med.nyu.edu/housestaff/PDguide/public/CredPolicy06.pdf Which outlines the credentialing requirements. No resident will be 'cleared' to begin training, without submitting the proper credential documents. Additionally, the IT department has developed a "look-up" intranet web application for the Nursing Staff to use to verify that a house officer has completed the credentialing process and has been cleared to work in the facility. **Time of Implementation:** The application will be operational and available January 1, 2007	
S 257	405.4 (a) (1) MEDICAL STAFF. Medical staff accountability. (1) The medical staff shall establish objective standards of care and conduct to be followed by all practitioners granted privileges at the hospital. This Regulation is not met as evidenced by: Based on medical record review, it was determined that the surgeon entered false	S 257		

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S 257	Continued From page 2 information on the operative report. (#1) Findings include: Review of MR#2 on 7/28/06 indicated that a CT of the abdomen done on the patient did not demonstrate any evidence of appendicitis. The patient was one week post-operative gastric banding, with an abscess at the port site. Review of the operative report indicated that the surgeon documented that the pre-operative diagnoses included appendicitis and that an appendectomy was performed. The patient was part of an FDA study in the area of gastric banding. The appendix was not sent for pathology. Tissues sent for microbiology yielded gram positive bacteria which were not consistent with appendicitis.	S 257	S 257 405.4 (a) (1) This case has been carefully peer reviewed and we do not agree that the surgeon entered false information on the operative report. Critical assessment of the medical record, suggests that the surgeon probably misinterpreted his operative findings. Because he visualized "no gross sepsis in the subdiaphragmatic area, around the band or above the liver," and because he found "gross pus in the lower abdomen, particularly in the pelvis and the right iliac fossa," we are persuaded that he assumed that the infection did not begin in the gastric band device. Furthermore, because he did not find the appendix, we believe he assumed that it had completely disintegrated. This occurs in ruptured appendicitis. In the dictated OR report he does not state that he removed the appendix. *See Attachment E* Furthermore, the surgeon reported this event to the IRB and the FDA as ruptured appendicitis but did not state that an appendectomy was performed. *See Attachment F* It is not uncommon for the operative findings to be in conflict with the pre-operative CT findings. There have been case reports of perforated appendicitis in children secondary to hemolytic streptococcus (Ped Infect Dis J 23:468-70, 2004) but the culture results were not known until after the operation. Finally, despite possible criticism of the surgeon's interpretation of his O.R. findings, we believe his diagnosis was made in good faith and that the re-operation he performed was the correct one. He properly took out the infected foreign body, did an open laparotomy to drain infected material, and placed five Jackson-Pratt drains. His judgment and decision-making were sound. *Attachment G*	
S 258	405.4 (a) (1) (i) MEDICAL STAFF. Medical staff accountability. (1) The medical staff shall establish objective standards of care and conduct to be followed by all practitioners granted privileges at the hospital. Those standards shall: (i) be consistent with prevailing standards of medical and other licensed health care practitioner standards of practice and conduct. This Regulation is not met as evidenced by: Based on medical record review and staff interview, it was determined that the facility failed to ensure that patients were provided with care that conformed to current standards of medical practice (#1). Findings include: Review of MR#1 on 7/28/06 indicated that the	S 258		

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S 258	Continued From page 3 surgical staff failed to address the persistent oliguria in a new post-operative patient. The patient went into cardiac arrest approximately 36 hours later. Review of the intake and output records indicated that the patient's output was 350 ml of urine over a 40 hour period and that no interventions were implemented. The patient was placed on a regular medical floor early in the post-operative period, even though she underwent 4 hours of complex surgery. The procedure was converted from a laparoscopic approach to a laparotomy, which was, in effect 2 consecutive procedures by 2 different surgeons. The patient had significant co-morbidities. Review of the post-operative care demonstrated that there was no foley catheter inserted to measure urinary output after a 4 hour procedure. No CBC or SMA to determine the patient's electrolyte status was done. There was, no fluid challenge and no CVP line inserted. There was no evidence of a level of monitoring consistent with that to be provided a patient who had a 4 hour procedure.	S 258	S 258 405.4 (a) (1) (I) The hospital became aware of this case on 8/14/06 and this case was reported to NYPORTS on 8/15/06 as an unexpected death following surgical treatment of obesity. An RCA was submitted on 10/13/06 *See Attachment H* The non-accredited program in bariatric surgery was terminated. The bariatric service has subsequently been covered by general surgery residents exclusively and as of July 1, 2006 has its own separate team of 2 general surgery residents including PGY1 and PGY 3 or 4 *See Attachment I* In addition, as of January 1, 2007 all bariatric patients will be covered 24/7 exclusively by a bariatric attending surgeon. *See Attachment I*	
S 328	405.4 (g) (1-2) (i-iii) MEDICAL STAFF. Unlicensed physicians. Patient care services may be provided by unlicensed physicians only under the following circumstances: (1) physicians not licensed by New York State but who practice within the exemptions authorized by section 6525 of the State Education Law; or (2) physicians who possess limited permits to practice medicine issued by the New York State Education Department pursuant to section 6525 of the State Education Law if such physicians are under the supervision of a physician licensed and	S 328	S328 405.4 (g) (1-2) (i-iii) & S331 405.4 (g) (3) (iii) The following Policy and Procedure was incorporated into the Medical Staff Rules and Regulations as of December 6, 2006 Policy Limited Permits A physician with a limited permit shall be granted the privilege to practice medicine only under the supervision of a licensed physician and in the hospital or hospitals identified on the permit. The following persons shall be eligible for a limited permit: (1) A person who fulfills all requirements for a license as a physician except those relating to the examination and citizenship or permanent residence in the United States; (2) A foreign physician who holds a	

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S 328	Continued From page 4	S 328		

currently registered to practice medicine in the State of New York and if the physicians possessing limited permits are:

(i) graduates of medical school offering a medical program accredited by the Liaison Committee on Medical Education or the American Osteopathic Association, or registered with the State Education Department or accredited by an accrediting organization acceptable to the State Education Department, and have satisfactorily completed one year of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department;

(ii) graduates of a foreign medical school and have satisfactorily completed three years of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department; or

(iii) graduates of a foreign medical school who have satisfactorily completed three years in a postgraduate training program and who are receiving advanced training as part of an official exchange visitor program approved by the United States Information Agency and the Educational Commission for Foreign Medical Graduates (ECFMG).

This Regulation is not met as evidenced by:
Based on medical record review, it was determined that the facility permitted two unlicensed physicians to practice medicine in the hospital without limited permits. (#1)

standard certificate from the educational council for foreign medical graduates or who has passed an examination satisfactory to the state board for medicine and in accordance with the commissioner's regulations; or (3) A foreign physician or a foreign intern who is in this country on a non-immigration visa for the continuation of medical study, pursuant to the exchange student program of the United States department of state.

The Medical Staff shall: (i) review the licensure, education, training, physical and mental capacity, and experience of all physicians practicing at the Hospital under a limited permit; (ii) based on written criteria, recommend privileges that are specific to treatments or procedures for each individual prior to delivery of patient care services; (iii) continuously monitor patient care services provided by such individuals to assure provision of quality patient care services within the scope of privileges granted; and (iv) take disciplinary action or other corrective measures against the individual providing service and/or the attending/supervising physician when services provided exceed the scope of privileges granted. *See Attachment J for procedure*

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S 328	Continued From page 5 Review of records indicated that the facility permitted two unlicensed physicians, without limited permits, to engage in the practice of surgery for periods of 4 months in 2004 and 2005 respectively. During that period, the physicians performed multiple surgical procedures, made pre and post op assessments and wrote orders to be carried out by nursing staff. During interview with administration on 8/18/06, it was stated that despite the fact that the physicians were not on the facility's payroll, they were issued identification cards and granted other accesses, leading other departments to assume that they had been properly credentialed.	S 328	S 134 405.2 (c) (1) 181 405.3 & S 328 405.4 (g) (1-2) (i-iii) Two areas were identified as weaknesses in the credentialing process. The first was that house staffs were given their ID badges prior to completing the credentialing process. Effective June 2006 the Security office no longer issues the NYU ID badge to house staff that have not cleared credentialing process. The second weakness noted was that computer access was granted prior to the resident completing the credentialing process. This has also been corrected. Health Information System access must be granted to allow the resident to train on the system, in advance of starting at NYU. Effective June 2006, if a resident does not 'clear' (complete the credentialing process) by their anticipated start date, then the Health Information System access is turned off until such time as they are cleared to begin resident training.	
S 330	405.4 (g) (3) (ii) MEDICAL STAFF. Unlicensed physicians. (3) the medical staff shall: (ii) based on written criteria, recommend privileges that are specific to treatments/procedures for each individual prior to delivery of patient care services. This Regulation is not met as evidenced by: Based on record review and interview, it was determined that the facility failed to formulate and implement a policy and procedure governing the practice of those persons who possess a limited permit to practice medicine. Findings include: During the onsite visit on 7/28/06 the facility was not able to provide the surveyor with any evidence of a policy and procedure that was formulated to govern the practice of physicians with limited permits in the facility.	S 330	We have a credentialing policy, which can be found at the link below and copy attached. *See Attachment D* http://www.med.nyu.edu/housestaff/PDguide/public/CredPolicy06.pdf Which outlines the credentialing requirements. No resident will be 'cleared' to begin training, without submitting the proper credential documents. Additionally, the IT department has developed a "look-up" intranet web application for the Nursing Staff to use to verify that a house officer has completed the credentialing process and has been cleared to work in the facility. **Time of Implementation:** The application will be operational and available January 1, 2007	

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S 330	Continued From page 6 During interview with Risk Management staff on 8/15/06, it was stated that no policy and procedure has been promulgated to regulate the practice of physicians with limited permits. Review of documents noted that a surgeon with a limited permit was supervising fellows, as well as directing the gastric banding program at the facility. S 331 405.4 (g) (3) (iii) MEDICAL STAFF. Unlicensed physicians. (3) the medical staff shall: (iii) continuously monitor patient care services provided by such individuals to assure provision of quality patient care services within the scope of privileges granted. This Regulation is not met as evidenced by: Based on review of records, it was determined that the facility failed to supervise the practice of unlicensed physicians with limited permits. Findings include: The facility was unable to provide the surveyor with any policy and procedure that governs the supervision of those physicians who are permitted to practice with a limited permit. A physician from a foreign country was acting as an attending surgeon, teaching fellows and supervising their practice, with no license to practice medicine in New York State. The physician had a limited permit. The individual who signed the permit did not exercise any actual supervisory duties over this	S 330 S 331	S328 405.4 (g) (1-2) (i-iii) & S331 405.4 (g) (3) (iii) The following Policy and Procedure was incorporated into the Medical Staff Rules and Regulations as of December 6, 2006 Policy Limited Permits A physician with a limited permit shall be granted the privilege to practice medicine only under the supervision of a licensed physician and in the hospital or hospitals identified on the permit. The following persons shall be eligible for a limited permit: (1) A person who fulfills all requirements for a license as a physician except those relating to the examination and citizenship or permanent residence in the United States; (2) A foreign physician who holds a standard certificate from the educational council for foreign medical graduates or who has passed an examination satisfactory to the state board for medicine and in accordance with the commissioner's regulations; or (3) A foreign physician or a foreign intern who is in this country on a non-immigration visa for the continuation of medical study, pursuant to the exchange student program of the United States department of state. The Medical Staff shall: (i) review the licensure, education, training, physical and mental capacity, and experience of all physicians practicing at the Hospital under a limited permit; (ii) based on written criteria, recommend privileges that are specific to treatments or procedures for each individual prior to delivery of patient care services; (iii) continuously monitor patient care services provided by such individuals to assure provision of quality patient care services within the scope of privileges granted; and (iv) take disciplinary action or other corrective measures against the individual providing service and/or the attending/supervising physician when services provided exceed the scope of privileges granted. *See Attachment J for procedure*	

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S 331	Continued From page 7 physician	S 331		
S 354	405.5 (b) (1) (iii) NURSING SERVICES. Delivery of services. (1) (iii) The hospital shall develop and implement policies and procedures for prompt review and correction, as necessary, of health care practitioner orders which have, or have the likely potential for having, negative impact on patient care and safety and which should not be carried out. This Regulation is not met as evidenced by: Based on record review and interview, it was determined that the nursing department failed to formulate and implement a procedure to ensure that nursing staff only follow the physician orders issued by persons who are legally authorized to write them. Findings include: During interview on 7/28/06, the facility was not able to provide the surveyor with evidence that the nursing department interacted with the department of medicine to ensure that nurses were not executing orders of persons who were not legally authorized to write them. Review of documents noted that the operating room staff permitted two unlicensed persons to act as assistant surgeons in the operating room, without nursing staff checking their credentials. During interview with administrative staff on 8/24/06 it was stated that nursing staff can only access the credentials of attending physicians, not those of residents or fellows. The staff must rely on the information noted on the practitioners'	S 354	S354 405.5 (b) (1) (iii) The IT department has developed a "look-up" intranet web application for the Nursing Staff to use to verify that a house officer has completed the credentialing process and has been cleared to work in the facility.	

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S 354	Continued From page 8 ID cards.	S 354		